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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,448	11/07/2001	Sidney N. Wolfe	PP16166.003	5486

7590 10/28/2004

Chiron Corporation  
Intellectual Property Department  
P.O. Box 8097  
Emeryville, CA 94662-8097

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/010,448	<b>Applicant(s)</b> WOLFE ET AL.	
	<b>Examiner</b> Janet L. Andres	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 and 30-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28, 30-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 17 August 2004 is acknowledged. Claims 1-28 and 30-78 are pending and under examination in this office action. Applicant's comments with respect to cancelled claim 29 are noted; the error is regretted. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained***

3. The rejection of claims 1-28 and 30-78 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "biologically active" is maintained for reasons of record in the office action of 23 March 2004.

Applicant argues that one of skill in the art would readily understand what was encompassed by the term "biologically active" when the claims were read in light of the specification. Applicant argues that the specification teaches that biologically active variants of IFN- $\beta$  retain IFN- $\beta$  activities, in particular the ability to bind IFN- $\beta$  receptors, and that the specification describes means for measuring such activities.

Applicant's arguments have been fully considered but have not been found to be persuasive. While many activities of IFN- $\beta$  are known in the art, the specification does not define what would be considered to be a biological activity. The artisan would not know if a molecule that retained the ability to generate an antibody would be considered to be "biologically active", for example. The activity particularly pointed to by Applicant, receptor binding, does not require that any physiological event occur after binding and thus molecules that the artisan

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would consider to be inactive could be encompassed. Furthermore, there is no IFN- $\beta$  receptor; there is a type I receptor to which IFN- $\alpha$  also binds. Thus, the artisan, interpreting the meaning of “biologically active” in light of the specification, would not know if Applicants intended to claim molecules as “biologically active” that had no actual biological activity, and would not know what if Applicant further intended to identify these molecules merely by their ability to bind to the type I receptor. Thus the claims do not serve the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. (MPEP §2173.02).

4. The rejection of claims 1-28 and 30-78 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims is maintained for reasons of record in the office action of 23 March 2004.

Applicant argues that the enablement requirement is met if the description enables any form of making and using the invention. Applicant states that the specification describes means of making the required mannitol. Applicant further argues that claims would be invalid for lack of enablement only if all of the disclosed methods were inoperative, pointing to *Engel, Johns Hopkins*, and *Durel*.

Applicant's arguments have been fully considered but have not been found to be persuasive. The claims were not rejected as lacking enablement. They were rejected as lacking enablement commensurate in scope with the claims. MPEP §2164.08 states,

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

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Here, the claims are broadly drawn to encompass all forms of “highly purified mannitol” having a “low” but unspecified level of reducing activity. By Applicant’s own teaching, the characteristics of this mannitol are crucial. Applicant has disclosed one method of making mannitol with these special characteristics. Applicant has argued persuasively in the response of 29 December 2003 that the prior art neither teaches nor renders obvious any methods using this special form of mannitol. However, the specification neither teaches any other means of making this crucial reagent nor provides means of recognizing any forms of mannitol made by other means that would be useful. The requirement for “low” reducing activity, with no guidance as to what is meant by “low” is not sufficient to identify forms with the desirable characteristics, if in fact they and means of making them are known in the art. Thus, since the claims are broadly drawn to encompass methods using “highly purified mannitol” with no other requirements as to the characteristics, Applicant teaches only one method of making such mannitol, there is no direction as to what other highly purified mannitols could be used or how they could be made, and since this reagent is crucial to the success of the invention, it would require undue experimentation for the artisan to practice it as broadly claimed.

**NO CLAIM IS ALLOWED.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
25 October 2004

  
JANET ANDRES  
PRIMARY EXAMINER